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DICKINSON, PAUL W				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/696,829

Applicant(s)

KREITZ ET AL.

Examiner

PAUL DICKINSON

Art Unit

4173

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 15-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 11/28/2007, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-10, 14, 30-33 have been cancelled. Claims 11-13, 15-29 are pending and currently under consideration.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 11-12, 14, 27-28 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 has been cancelled and the rejection is therefore moot. Claims 11, 12, 27 and 28 were amended. Applicant's arguments with respect to the amended claims have been fully considered and are persuasive. The rejection of Claims 11-12, 27-28 under 35 U.S.C. 112, second paragraph, is therefore withdrawn.

Claim Rejections - 35 USC § 102

Claims 22-29 were rejected under 35 U.S.C. 102(b) as being anticipated by Gittins et al. Applicant amended Claim 22 to clearly define the nanoparticles as

comprising taxane. Applicant argues that Gittins discloses a metal nanoparticle and not a particle formed of a taxane. Applicant's arguments with respect to the amended claims have been fully considered and are found persuasive. The rejection of Claims 22-29 under 35 U.S.C. 102(b) as being anticipated by Gittens et al is therefore withdrawn.

Claims 11-15, 17-18, 21-29 were rejected under 35 U.S.C. 102(b) as being anticipated by Sharma et al. Applicant cancelled Claim 14. Applicant amended Claims 11 to define the nanoparticles as non-polymeric encapsulated nanoparticles. Claim 22 has been amended to clearly define the nanoparticles as comprising taxane. Applicant argues that Sharma et al describes polyvinylpyrrolidone nanoparticles of Taxol but does not describe non-polymer encapsulated nanoparticles. Applicant further argues that Sharma does not disclose oral administration. In addition, Sharma et al teaches away from nanoparticles which are not polymer encapsulated. Applicant's arguments with respect to the amended claims have been fully considered and are not found persuasive.

Claim 11 now clearly requires a population of non-polymer encapsulated nanoparticles. While the method disclosed by Sharma et al produces a formulation comprising predominantly polymer-encapsulated nanoparticles of Taxol (paclitaxel), the same formulation must also comprise a population of non-polymer encapsulated Taxol nanoparticles. The disclosed encapsulation is an equilibrium process, and at least a small population of Taxol nanoparticles would reasonably be produced in the product

formulation. This argument is supported by implementation of a dialysis bag to remove the polymer-encapsulated nanoparticles from unreacted small molecules, and the disclosed encapsulation efficiency of about 85% (see p 282, Preparation of Taxol-loaded nanoparticles).

Claims 12-13 are directed to water-insoluble agents. As stated in the office action, paclitaxel is a water-insoluble agent (see page 7).

Claim 22 now includes the phrase "...for oral administration of a taxane wherein the non-polymer encapsulated nanoparticles comprise taxane and the formulation has a bioavailability when administered orally of at least 5% of the bioavailability of the taxane when administered intravenously." As stated above, Claim 22 now clearly defines the nanoparticles as comprising taxane. Oral administration of a taxane is, however, an intended use and is not given patentable weight. The Examiner agrees that Sharma et al does not teach oral administration of the disclosed formulation. Any non-polymer encapsulated nano or microparticulate formulation wherein the non-polymer encapsulated nanoparticles comprise taxane would, however, read on the Claim 22. Therefore, the formulation disclosed by Sharma et al still anticipates the Instant Claim. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

The Examiner agrees that Sharma et al teaches that administration of polymeric nanoparticles is an improvement over administration of free Taxol (see p 285, first column). The Examiner does not, however, consider this a teaching away from administration of free Taxol. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). MPEP 2123, II.

This notwithstanding, whether or not Sharma et al teaches away from the instant invention is not relevant to a rejection under 35 U.S.C. 102(b). "Arguments that the alleged anticipatory prior art is nonanalogous art or teaches away from the invention or is not recognized as solving the problem solved by the claimed invention, [are] not germane to a rejection under section 102." Twin Disc, Inc. v. United States, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting In re Self, 671 F.2d 1344, 213 USPQ 1, 7 (CCPA 1982)). See also State Contracting & Eng'g Corp. v. Condotte America, Inc., 346 F.3d 1057, 1068, 68 USPQ2d 1481, 1488 (Fed. Cir. 2003).

The rejection of Claims 11-13, 15, 17-18, 21-29 under 35 U.S.C. 102(b) as being anticipated by Sharma et al is maintained.

Claim Rejections - 35 USC § 103

Claims 16, 19-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al in view of Santos et al. Applicant argues that Sharma et al teaches away from a non-polymer encapsulated nanoparticle formulation, and does not disclose any formulation suitable for oral administration. Furthermore, Santos does not make up for this deficiency. Santos describes bioadhesive formulations, all of which utilize polymers as the bioadhesive. Applicant's arguments with respect to the amended claims have been fully considered and are not found persuasive.

As stated above, Sharma et al teaches that administration of polymeric nanoparticles is an improvement over administration of free Taxol, but does not teach away from the administration of free Taxol.

The Examiner agrees that Santos et al describes bioadhesive formulations which utilize polymers as the bioadhesive agent. This fact does not affect the motivation set forth in the office action to combine the disclosures above and add a bioadhesive agent to the formulation disclosed by Santos et al. In addition, the Examiner finds the polymers disclosed by Santos et al to be reasonably encompassed by the term "bioadhesive agent" provided by the Instant Claims and Specification (see ¶¶ 47, 55, 62).

The rejection of Claims 16, 19-20 under 35 U.S.C. 103(a) as being unpatentable over Sharma et al in view of Santos et al is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **PAUL DICKINSON** whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W. Dickinson
Examiner
AU 4173

January 17, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614